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510(k) Summary

K 010104

General Information:

This 510(k) is to provide notification of substantial equivalence for the Candela Long Pulse Nd:YAG Laser system, which is substantially equivalent to previously marketed devices intended for use in dermatology for The removal of unwanted hair in all skin, types I through VI, Photocoagulation and hemostasis of pigmented and vascular lesions, coagulation and hemostasis of soft tissue.

Submitted by:	Candela Corporation 530 Boston Post Road Wayland, MA 01778-1886
Contact Person:	Joan M. Clifford
Date prepared:	January 10, 2001
Trade Name:	Candela Long Pulse Nd:YAG
Common Name:	Dermatology Laser System
Classification:	Class II (21 CFR § 878.4810 Laser Surgical Instrument for use in General and Plastic Surgery and in Dermatology)
Predicate Device:	Altus CoolGlide Nd:YAG (K991798), LaserScope Lyra and Lyra-XP (K990718, K990903), Cosmos Athos (K001704), and ESC VascuLight, PhotoDerm Nd:YAG Accessory (K980537).

Description:
The Candela Nd:YAG Laser System is a 1064 nm wavelength Nd:YAG medical laser, controlled by an embedded processor, to be used for laser treatment of removal of hair and vascular lesions, and coagulation of soft tissue. The laser system will be used in conjunction with the Dynamic Cooling Device that provides a short burst of cryogen spray during the laser pulse. The laser output energy is delivered via an optical fiber to a slider spot size. The embedded microprocessor provides a user interface via a control panel located on the laser exterior that allows the operator to select the operating parameters of the system.

The laser has the ability to calibrate the output energy of the handpiece to the fluence level selected by the operator. Once the energy has been calibrated, the laser can deliver a single pulse or be pulsed at a repetition rate of up to 2Hz (continuously). The energy at the laser head is monitored and controlled by adjusting the current supplied to the laser Nd:YAGs.

The Candela Long pulse Nd:YAG is comprised of a power supply, optical delivery system, software control system and Dynamic Cooling Device.

The Candela Long pulse Nd:YAG is equipped with safety interlock systems to protect patients and operators. Users of the device make selections from a control panel to regulate operation during treatment.

Testing:
As a laser product, the Long pulse Nd:Yag is required to conform and does conform to the Laser Performance Standard (21 CFR 1040). In addition, the device will conform to the UL 544 electrical safety standard and the Essential Requirements of the European Union Medical Device Directives.

Summary of Substantial Equivalence:
The Candela Long pulse Nd:YAG has the same intended use, utilizes similar operating principles, matches key design aspects, including similar spot size, wavelength and the similar maximum delivered power as the predicate devices. On this basis, Candela believes that its Candela Long pulse Nd:YAG is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Ms. Joan Clifford
Director of Regulatory Affairs
Candela Corporation
530 Boston Post Road
Wayland, Massachusetts 01778

Re: K010104
Trade/Device Name: Candela Long Pulse Nd:YAG
Regulation Number: 878.4810
Regulatory Class: II
Product Code: GEX
Dated: January 10, 2001
Received: January 12, 2001

Dear Ms. Clifford:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K010104

Device Name: Candela Long pulse Nd:YAG

Indications For Use:

The Candela Long pulse Nd:YAG Laser is indicated for the following uses:
For the removal of unwanted hair in all skin types (Fitzpatrick types I through VI), photocoagulation and hemostasis of pigmented and vascular lesions, such as leg veins, and coagulation and hemostasis of soft tissue.

The intended use of the Candela Dynamic Cooling Device is:
Cooling of the skin prior to laser treatment.
For the reduction of pain during laser treatment.
Allows for use of higher fluences for laser treatments, such as for hair removal, vascular lesions.
Reduces potential side effects of laser treatments, such as for hair removal and vascular lesions.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(Optional format 1-2-96)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K010104